

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/027,073 Confirmation No. 9825
Applicant : William C. Dengler
Filed: : December 20, 2001
Title: : INTERNET-BASED INTEGRATED HEALTHCARE
DELIVERY SYSTEM AND PROCESS
TC/ Art Unit : 3626
Examiner : BLECK, C. M.
Atty Docket No. : 2824/1
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Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF PURSUANT TO 37 C.F.R § 41.37

Sir:

This Appeal Brief is being submitted further to the Notice of Appeal filed September 1, 2006, in response to the FINAL Office Action mailed June 16, 2006. The Appeal Brief is accompanied by the fee set forth in § 41.20(b)(2). A petition for four (4) months extension of time until March 1, 2007, along with the requisite fee, is also being submitted herewith pursuant to 37 C.F.R. §§ 1.136(a) and 1.17(a)(4). Accordingly, this Appeal Brief is being timely filed and Appellant respectfully requests the Examiner to enter the Appeal Brief on the record.

(i) Real party in interest

The real party in interest is Legato Medical Systems, Inc., of Raleigh, North Carolina, which acquired the entire right, title and interest in and to the application and the invention(s) disclosed therein by assignment from the named inventor William C. Dengler.

(ii) Related appeals and interferences

There are no other prior or pending appeals, interferences or judicial proceedings known to Appellant, the Appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(iii) Status of claims

The subject application was originally filed with claims 1-28. Claims 1-13, 27 and 28 were canceled, claims 14 and 16 were amended, and new claims 29-32 were presented for examination by the Amendment dated September 24, 2003. Claims 14 and 29 were amended by the first Request For Continued Examination (first RCE) filed May 18, 2004. Claims 14-26 and 29-32 were canceled and new claims 33-46 were presented for examination by the second Request For Continued Examination (second RCE) filed September 23, 2005. Claims 33, 36, 37, 39, 40, 43 and 44 were amended

and new claims 47-49 were presented for examination by the Amendment dated May 15, 2006. As a result, claims 1-32 stand canceled and claims 33-49 stand rejected. The rejections of claims 33-49 from the FINAL Office Action mailed June 16, 2006, are being appealed in this appeal.

(iv) Status of amendments

No amendment has been filed subsequent to the FINAL Office Action mailed June 16, 2006. Accordingly, the Amendment dated May 15, 2006, is the last amendment admitted by the Examiner into the record prior to this appeal.

(v) Summary of claimed subject matter

The invention provides a unique system and method that integrates the delivery of healthcare services by multiple healthcare providers to a patient so that the patient can receive comprehensive treatment for his or her medical condition without having to resort to self-management of a confusing maze of medical records, appointments, and treatment options. Specification at para. [0004]. Unlike prior art systems having software that dictates to the user the type of medical care to be provided to the patient, the system and method of the present invention serves as a management tool for assimilating all medical records (i.e. test results) and information regarding a patient at a central location (i.e. a database) so that a healthcare provider can more efficiently utilize

the records and information to make decisions regarding treatment for the patient. Specification at para. [0005].

The presently claimed embodiments of the invention relate to a method of coordinating delivery and integrating management of healthcare services from multiple healthcare providers 18 to effectively treat a patient 16 having a selected medical condition, such as gastroesophageal reflux disease (GERD). See FIG. 1. The method comprises providing a computerized information management system including a server 24 and at least one computer 28. The server includes a database 22 operable to receive and store data regarding the patient for retrieval from the database. Specification at para. [0059]; FIG. 2. The computer communicates with the database via a communications network (e.g. Internet) 34 to permit a user (i.e. coordinating party 14; patient 16; healthcare provider 18; system administrator 39) to access the data. The method further includes selecting a plurality of tests 72 (from a menu of tests 70) to be conducted on the patient to assist in diagnosing the selected medical condition, or an aspect thereof. Specification at para. [0065]; FIG. 7, step 65. A list of the tests 72 is then stored in the database so as to enable a user to track the completion status of the tests via the computer. Specification at para. [0067]; FIG. 7, step 65. The method further includes using the computer to solicit from a user a subset of test results selected from the set of possible results for that test. Specification at para. [0069]; FIG. 8, step 96. The subset of test results is then stored in the database. Id. The method

further includes creating a summary 108 which simultaneously displays the subsets of test results for all of the selected tests for use by a healthcare provider in selecting a treatment track for treatment of the selected medical condition based on the test results. Specification at para [0070]; FIG. 8; FIG. 15A; FIG. 15B. The summary is then stored in the database. Specification at para. [0070]. In a preferred embodiment, the treatment track comprises a preselected event selected from the group consisting of a lifestyle change, a prescription for medication, an appointment with a healthcare provider, an outpatient procedure, and an inpatient procedure for treating the selected medical condition. Id.

(vi) Grounds of rejection to be reviewed on appeal

The following grounds of rejection are to be reviewed pursuant to this appeal:

1. Rejection of claims 33-39 under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. (6,018,713) in view of Bair et al. (6,108,665);
2. Rejection of claims 40-46 [sic: 48] under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. in view of Bair et al. and Teagarden et al. (6,104,631); and
3. Rejection of claim 49 under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. in view of Bair et al., as applied to claim 33, and further in view of Kraftson (6,151,581)

(vii) Argument

I. Grounds for rejection of pending claims 33-49

1. Rejection of claims 33-39 under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. (6,018,713) in view of Bair et al. (6,108,665);

The Examiner asserts that independent claim 33 is obvious over Coli et al. in view of Bair et al. In particular, the Examiner asserts that Coli et al. discloses:

(2) “for each of the tests, using the computer to solicit from the user a subset of test results selected from the set of possible results for that test; and storing the subset of test results in the database; ...”; and

(3) creating a summary “which simultaneously displays the subsets of test results for all of the selected tests” for use by a healthcare provider in selecting a treatment track for treatment of the “selected condition” based on the test results, and storing the summary in the database.”

FINAL Office Action mailed June 16, 2006, at pages 3-4.

Appellant respectfully submits that the Examiner misinterprets the quoted claim limitations excerpted from claim 33. For each of the tests selected in step (b), the claimed invention requires “using the computer to solicit from the user a subset of test results selected from the set of possible test results for that test.” The claimed invention subsequently requires “creating a summary which simultaneously displays the subsets

of test results for all of the selected tests” [i.e. tests selected in step (b)] “for use by a health care provider in selecting a treatment track for treatment of the selected medical condition based on the test results.” The intended meaning of these patentable limitations in claim 33 is best described in the Specification of the application at paragraphs [0069] and [0070], which are reproduced below with emphasis given to the most relevant portions:

[0069] Referring again to Figure 8, the patient plan of care 92A and physician plan of care 92B are used as guides in executing step 94 of the treatment process 60. During step 94, all of the diagnostic tests that were scheduled as part of step 65 (see Figure 7) are performed. As is set forth in step 96, after each test is performed, the coordinating party 14 contacts the healthcare provider 18 responsible for conducting the test and obtains the test results. Once the test results have been gathered, the coordinating party returns to the Web site 26, and enters the test results for each test on its respective appointment page by responding to customizable multiple-choice questions related to the test or by entering textual data into free-entry-text fields. For example, the appointment page 68 shown in Figure 9 includes a series of questions regarding the results of the therapeutic endoscopy test. Each question is paired with a pull-down menu 100. The coordinating party 14 uses each pull-down menu 100 to select textual description data 102 representing the answer to the question appearing above the respective pull-down menu 100. Any revision made to the answers provided deselects

the previous answer and selects the new answer chosen. After the results are entered, the coordinating party 14 saves the changes made to the appointment page 68 before entering other test result data.

[0070] Referring again to Figure 8, once all of the test results have been entered, the coordinating party 14 executes step 104 of the treatment process 60 by utilizing the software program 20 to publish a summary 108 of the test results for the patient 16. The summary 108 is downloaded to a database 22 on the server 24 (see Figure 2) and is forwarded or otherwise made available to any PCP 18A, specialist 18E, or other selected healthcare providers involved in the treatment process 60. A representative sample of a summary 108 is shown in Figures 15A and 15B. The summary 108 is also used during the scheduled follow-up appointment which occurs as part of step 106 of the treatment process 60. During the follow-up appointment, the patient 16 and the PCP 18A or specialist 18E mutually decide upon a treatment track 109 for the patient 16. The treatment track 109 may include, but is not limited to non-surgical treatment 110, which may incorporate lifestyle changes and medications, an outpatient procedure 112 such as endoscopy, and/or an inpatient procedure 114 such as minimally invasive laparoscopic fundoplication.

See also, FIGS. 7; 8; 15A; 15B.

Coli et al. teaches an integrated system and method for ordering medical tests and for reporting cumulative results of the medical tests. A user may choose to

generate a test data report from a hospital computer 202 or a physician computer 206 in order to review the lab's progress towards completion of scheduled tests as well as to review completed test results. Column 13, lines 30-35. A range of dates for cumulative results/status reporting can be selected. In contrast to the claimed invention, "the physician can select particular categories of test results to be viewed" and "obtain results of tests in the indicated categories." "For this purpose, the tests are grouped using the same method used for grouping tests for ordering purposes" ... which "provides a consistent and clinically sensible interface for the physician when ordering tests and reviewing the results of those tests." Column 13, lines 46-53; FIG. 10; FIG. 11.

In other words, the physician can select a subset of tests from the set of tests previously ordered for the patient from particular categories of tests organized in meaningful clinical groupings (see column 11, lines 27-30). However, the computer is not used to solicit from the physician (or any other user) a subset of test results selected from the set of possible test results for that test. See Specification at para. [0069]; FIG. 9. Furthermore, the physician (or any other user) is not able to create a summary which simultaneously displays the subsets of test results (selected from the set of possible test results) for all of the tests previously ordered. At best, the physician can only display a subset of the tests previously ordered for the patient that are arranged in the same meaningful clinical groupings. The physician would then have to take the next step of

extracting the test results from the subsets of tests displayed in the meaningful clinical groupings to obtain the same benefits as the claimed invention. Specifically, the physician would need to obtain a summary of the test results for use in selecting a treatment track for treatment of the selected medical condition based on the test results. Thus, Coli et al. does not identically disclose or arguably suggest the additional features of the claimed invention.

Bair et al. teaches a system and method for optimizing collection of behavioral health care data for a patient in order to assess and determine the patient's behavioral health condition. In a particular embodiment, selected information is electronically communicated to a data-collection center. In another embodiment, the system and method permits creation of customized questionnaires and comprises means for displaying and entering results for one or more tests chosen from a group of empirically validated assessments and custom questionnaires. However, Bair et al. does not disclose or arguably suggest using a computer to solicit from a user a subset of test results selected from the set of possible test results for that test. See Specification at para. [0069]; FIG. 9. Furthermore, the user is not able to create a summary which simultaneously displays the subsets of test results (selected from the set of possible test results) for all of the tests previously ordered. Accordingly, Bair et al. does not overcome the deficiencies of Coli et al. since the reference does not identically disclose or arguably suggest the additional features of the claimed invention.

It is duly noted that one cannot show non-obviousness by attacking references individually; and that the test for obviousness is not whether the features of a secondary reference can be bodily incorporated into the disclosure of the primary reference nor whether the claimed invention is expressly suggested in any one or all of the references. However, it is well settled that section 103 requires the invention to be considered as a whole, *Schenck, A. G. v. Nortron Corp.*, 713 F.2d782 (Fed. Cir. 1983), and that the combination of references proposed by the Examiner must produce the claimed invention. Furthermore, the Examiner must show some suggestion or motivation, before the invention itself, to make the proposed combination. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270 (Fed. Cir. 2004). "This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not 'evidence'." *Harmon*, Patents and the Federal Circuit, Seventh Edition, at page 208. In the present instance, Appellant submits that the Examiner has failed to establish the requisite prima facie obviousness embraced by the Federal Circuit for ex parte patent prosecution in the Patent Office since the prior art relied on by the Examiner does not compel the conclusion of obviousness in the absence of Applicant's evidence or argument to rebut it. In other words, the Examiner has not satisfied the initial burden for establishing obviousness because the combination of references does not produce the claimed invention, and even if the combination did produce the claimed invention, there is no objective evidence of suggestion or motivation in the prior art to

combine the references in the manner proposed by the Examiner. Without these, the Examiner cannot support the contention that the claimed invention would have been obvious to one of ordinary skill at the time the invention was made in view of the prior art.

For at least the above reasons, Appellant respectfully submits that the rejection of independent claim 33 under 35 U.S.C. 103(a) is improper and must be withdrawn. Claims 34-39 depend directly or indirectly from patentable base claim 33, and thus, are likewise allowable for at least the same reasons. Accordingly, Appellant respectfully requests the Board to reverse the Examiner's FINAL rejection of claims 33-39.

2. Rejection of claims 40-46 [sic: 48] under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. in view of Bair et al. and Teagarden et al. (6,104,631); and

The Examiner asserts that independent claim 40 is obvious over Coli et al. in view of Bair et al. and Teagarden et al. As discussed above, the combination of Coli et al. and Bair et al. proposed by the Examiner does not produce the claimed invention. Furthermore, there is no suggestion or motivation in the prior art to combine the references in the manner proposed by the Examiner. Teagarden et al. teaches a computer implemented patient medication review system and process designed to gather the therapeutic history of a patient, including medication use, adverse effects,

treatment goals, medical history and patient concerns and satisfaction. However, Teagarden et al. does not disclose or arguably suggest using a computer to solicit from a user a subset of test results selected from the set of possible test results for that test. See Specification at para. [0069]; FIG. 9. Furthermore, the user is not able to create a summary which simultaneously displays the subsets of test results (selected from the set of possible test results) for all of the tests previously ordered. Accordingly, Teagarden et al., alone or in combination with Bair et al., does not overcome the deficiencies of Coli et al. since the reference does not identically disclose or arguably suggest the additional features of the claimed invention. In fact, the Examiner does not expressly rely on the teaching of Teagarden et al. in any way to overcome the deficiencies of Coli et al. and Bair et al with respect to independent claim 40.

For at least the above reasons, Appellant respectfully submits that the rejection of independent claim 40 under 35 U.S.C. 103(a) is improper and must be withdrawn. Claims 41-48 depend directly or indirectly from patentable base claim 40, and thus, are likewise allowable for at least the same reasons. Accordingly, Appellant respectfully requests the Board to reverse the Examiner's FINAL rejection of claims 40-48.

3. Rejection of claim 49 under 35 U.S.C. 103(a) as being unpatentable (obvious) over Coli et al. in view of Bair et al., as applied to claim 33, and further in view of Kraftson (6,151,581)

The Examiner asserts that dependent claim 49 is obvious over Coli et al. in view of Bair et al., as applied to independent claim 33, and further in view of Kraftson et al. As discussed above, the combination of Coli et al. and Bair et al. proposed by the Examiner does not produce the claimed invention recited in independent claim 33. Furthermore, there is no suggestion or motivation in the prior art to combine the references in the manner proposed by the Examiner. Kraftson et al. teaches a system and method for building and administering a patient management and health care management database containing data relevant to the clinical care of patients, the management of the practices to which the patients belong, and to outcomes of that health care and practice management, through the administering, collecting, analyzing and summarizing patient surveys. However, Kraftson et al. does not disclose or arguably suggest using a computer to solicit from a user a subset of test results selected from the set of possible test results for that test. See Specification at para. [0069]; FIG. 9. Furthermore, the user is not able to create a summary which simultaneously displays the subsets of test results (selected from the set of possible test results) for all of the tests previously ordered. Accordingly, Kraftson et al. does not overcome the deficiencies of Coli et al. and Bair et al. since the reference does not identically disclose or arguably suggest the additional features of the claimed invention. Therefore, Appellant asserts that claim 49 stands or falls with independent claim 33.

For at least the above reasons, Appellant respectfully submits that the rejection of dependent claim 49 under 35 U.S.C. 103(a) is improper and must be withdrawn. Claim 49 depends directly from patentable base claim 33, and thus, is likewise allowable for at least the same reasons. Accordingly, Appellant respectfully requests the Board to reverse the Examiner's FINAL rejection of claim 49.

II. Applicant's Rule 132 Declaration

The Examiner's issued a final rejection of then-pending and now canceled claims 14-26 and 29-32 on the basis of obviousness in the FINAL Office Action mailed November 19, 2003. In response, Applicant submitted a first Request For Continued Examination (RCE) including the Declaration Under Rule 132 of Chalmers M. Nunn, Jr., MD attached hereto as Exhibit A. See Amendment filed May 18, 2004. The Declaration established that the Heartburn Treatment Center associated with the Lynchburg General Hospital in Lynchburg, Virginia experienced a dramatic increase in the number of surgical procedures, manometry procedures, pH studies and patient self-referrals since contracting with the assignee to utilize the Internet-based integrated healthcare delivery system and method of the claimed invention. See Declaration at para. 1-5, 8 and 10. The Examiner asserted that "there is no clear and definite nexus between the statements averred ... and Applicant's claims" and further argued that "[i]n order to establish commercial success, the evidence must establish that the alleged commercial

success is directly derived from the invention claimed.” Office Action mailed September 21, 2004 at pages 12-13. In particular, the Examiner stated:

However, it is not clear to the Examiner, based on the data in paragraphs 3-10, that the increase in the number of procedures was due to the use of the Internet-based integrated healthcare delivery system. The evidence presented does not rule out the possibility that the marketplace was such that consumption was by purchasers normally tied to Applicant or assignee, and as such, is insufficient to establish Applicant's allegations that such commercial interest stems from the commercial success directly derived from the invention claimed.

Id. at page 13. Appellant points out that the Heartburn Treatment Center is not the Applicant or the assignee of the claimed invention. As such, the Heartburn Treatment Center does not sell the claimed invention. Instead, it uses the claimed invention to sell healthcare services to patients, and in particular, to gastroenterology patients. Accordingly, the increase in procedures, tests and patients experienced by the Heartburn Treatment Center after beginning to use the Internet-based integrated healthcare delivery system which is the basis of the claimed invention is evidence that commercial success is being derived directly from the claimed invention sufficient to establish the required nexus between the merits of the claimed invention and the evidence proffered. See e.g., *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015 (Fed. Cir. 1985). Evidence of commercial success is relevant because the law

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presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art. *Merck & Co. v. Teva Pharm. USA Inc.*, 395 F.3d 1371 (Fed. Cir. 2005). Regardless, the Examiner must accept as true the statements of fact averred in a Declaration submitted under Rule 132 and the Applicant need not “rule out” all other possibilities.

(viii) Claims appendix

The following is an appendix listing the claims involved in this appeal:

33. A method of coordinating management of healthcare services for a patient having a selected medical condition, comprising:

- (a) providing a computerized information management system including:
 - (i) a server including a database operable to receive and store for retrieval data from an information source regarding a patient which is collected by a coordinating party; and
 - (ii) at least one computer communicating with the database via a communications network for processing the data so as to permit a user to access the data;
- (b) selecting a plurality of tests to be conducted on the patient, the tests selected to diagnose the selected medical condition or an aspect thereof; and storing in the database a list of the tests so as to enable tracking of the completion status of the tests using the computer;
- (c) for each of the tests, using the computer to solicit from the user a subset of test results selected from the set of possible results for that test; and storing the subset of test results in the database; and
- (d) creating a summary which simultaneously displays the subsets of test results for all of the selected tests for use by a health care provider in

selecting a treatment track for treatment of the selected medical condition based on the test results; and storing the summary in the database.

34. The method according to claim 33, wherein the communications network comprises a global communications network.

35. The method of claim 33, wherein the treatment track comprises a preselected event selected from the group consisting of a lifestyle change, a prescription for medication, an appointment with a healthcare provider, an outpatient procedure, and an inpatient procedure for treating the selected disease¹.

36. The method of claim 33, further including the step of providing the user access to the data by providing a Web site maintained by a system administrator and accessible by the user.

37. The method of claim 36, further comprising the step of providing a preselected password to the user for selectively permitting the user to access said Web site.

¹ It should be noted that "disease" lacks antecedent basis. Appellant submits that claim 46 should be amended by substituting "medical condition" therefore.

38. The method of claim 33 wherein said coordinating party is selected from the group consisting of a healthcare provider and a registered nurse.

39. A method of coordinating delivery of healthcare services according to claim 33, wherein said information source is selected from the group consisting of the patient, the user, and a healthcare provider.

40. A method of integrating management of healthcare services relating to gastroesophageal reflux disease (GERD), comprising:

- (a) providing a computerized information management system including:
 - (i) a server including a database configured to receive and store for retrieval data from an information source regarding a patient and collected by a coordinating party;
 - (ii) at least one computer communicating with the database via the communications network for processing the data for permitting a user to access the data²;
- (b) selecting a plurality of tests to be conducted on the patient, the tests selected to diagnose GERD or an aspect thereof; and storing in the

² In the Amendment dated May 15, 2006, the italicized words were inadvertently deleted by the amendment to claim 40. Appellant submits that independent claim 40 was intended to be amended in the same manner as independent claim 33.

database a list of the tests so as to enable tracking of the completion status of the tests using the computer;

- (c) for each of the tests, using the computer to solicit from a party a subset of test results selected from the set of possible results for that test; and storing the subset of test results in the database; and
- (d) creating a summary which simultaneously displays the subsets of test results for all of the selected tests for use by a health care provider in selecting a treatment track for treatment of GERD based on the test results; and storing the summary in the database.

41. The method according to claim 40, wherein the communications network comprises a global communications network.

42. The method of claim 40, wherein the treatment track comprises a preselected event selected from the group consisting of a lifestyle change, a prescription for medication, an appointment with a healthcare provider, an outpatient procedure, and an inpatient procedure for treating GERD.

43. The method of claim 40, further including the step of providing the user access to the data by providing a Web site maintained by a system administrator and accessible by the user.

44. The method of claim 43, further comprising the step of providing a preselected password to the user for selectively permitting the user to access said Web site.

45. The method of claim 40 wherein the coordinating party is selected from the group consisting of a healthcare provider and a registered nurse.

46. A method of coordinating delivery of healthcare services according to claim 40, wherein the information source is selected from the group consisting of the patient, the requesting party³, and a healthcare provider.

47. The method of claim 40, wherein the tests are selected from the group consisting of endoscopy, esophageal manometry, ph monitoring, X-rays, and gallbladder ultrasound.

³ It should be noted that "requesting party" lacks antecedent basis. Appellant submits that claim 46 should be amended in the same manner as corresponding claim 39 by substituting "user" therefor.

48. The method of claim 40, wherein the tests include: endoscopy, esophageal manometry, ambulatory ph monitoring, upper gastrointestinal X-rays, and gallbladder ultrasound.

49. The method of claim 33, further comprising the steps of:

- (a) creating and storing a survey schedule and prompting the coordinating party to conduct patient satisfaction surveys to monitor the patient's progress within the treatment track in accordance with the survey schedule; and
- (b) receiving the results of the patient satisfaction surveys in accordance with the survey schedule, and storing the survey results in the database.

(ix) Evidence appendix

The Declaration Under Rule 132 of Chalmers M. Nunn, Jr., MD submitted with the first RCE filed May 18, 2004, and entered into the record by the FINAL Office Action mailed September 21, 2004, is attached hereto as Exhibit A.

(x) Related proceedings appendix

Pursuant to section (ii) above, there are no proceedings related to this appeal.

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